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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,245	01/26/2001	Jeffrey Ray Stout	BO 44277	5103

466 7590 12/04/2001

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/04/2001

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,245

Applicant(s)

STOUT ET AL.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, 12, 14, 16, 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 9 recite "creatine salt" which renders the claims indefinite as same term is used in claim 5 which appears to be different in scope. To avoid confusion, Examiner suggests using "organic creatine salt".

Claim 9 recites "wherein the creatine salt comprises an anionic component" which renders the claim indefinite as the above impliedly excludes creatine since it is not recited after the transitional phrase "comprises". Examiner suggests using "further comprises".

Claim 12 recites the limitation "anionic component of the creatine salt". There is insufficient antecedent basis for this limitation in the claim. Neither Claim 11 nor Claim 1 recite the above.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 14 recites the broad recitations "creatine", "phosphorus" and "buffer", and the claim also recites "creatine citrate", "phosphate" and "a combination of carbonate and/or bicarbonate and citrate" which are the narrower statement of the range/limitations, respectively.

Art Unit: 1616

Claim 16 recites "pentose" and "ribose". Claim 17 recites "sodium salt" and "sodium phosphate".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardiner (U.S. Pat. 6,136,339) in view of Weinstein et al. (U.S. Pat. 6,013,290), WO 96/04240, Fang (U.S. Pat. 5,886,040), Webster's Dictionary (10th Ed.), Odian et al. (Schaum's Outline), Hultman et al. (U.S. Pat. 5,767,159) and St. Cyr et al. (U.S. Pat. 6,159,942).

Gardiner teaches a food supplement comprising creatine, including creatine monohydrate, creatine citrate and creatine pyruvate and phosphorous and salts thereof (Column 2, lines 20-24, Column 3, lines 34-39, Column 5, lines 5-55). A method of administration is taught where administration of the supplement continued until the desired muscle size or strength is obtained and then reduced amounts of the supplement is administered to maintain said muscle size or strength (Column 4, lines 47-60).

Weinstein et al. teaches that for person's who are exercising and replenishing lost water, sodium is necessary to prevent hyponatremia and allow optimal restoration of lost fluid (Column 4, lines 20-28). Is taught that carbohydrates are useful for recovery of muscle glycogen after exercising (Column 4, lines 30-68). It is taught that sodium bicarbonate, sodium citrate and potassium citrate are alkaline buffers improve performance in athletes utilizing the anaerobic

Art Unit: 1616

energy system by counteracting the increasing acidity of blood caused by exercise and which acidity contributes to fatigue (Column 5, lines 50-58). It is taught that creatine supplementation for allows high rates of ATP resynthesis (Column 6, lines 7-14). It is taught that phosphates and pyruvates have or may have positive effects on exercise (Column 6, lines 20-24).

WO 96/04240 teaches that mono-, bi- or tri-carboxylic acid salts of creatine, including citrate, maleate, fumarate, tartrate or malate, exhibit increased hydrosolubility and increased bioavailability over creatine, with the citrate, maleate and tartrate salts exhibiting a water solubility of 10 g/100 ml, 19 g/100 ml and 8.5 g/100 ml, respectively (Pgs. 1-3).

Fang teaches that creatine pyruvate is more water soluble than creatine and enables the optimal biofunctionality of both creatine and pyruvate in enhancing energy and metabolic rates (Column 8, lines 19-35).

Webster's Dictionary (10th Ed.) defines "precursor" as a substance from which another substance is formed (Pg. 917).

Oadian et al. teaches that in the Kreb's cycle, that pyruvate is used to form citrate fumarate and malate, that citrate is used to form fumarate and malate , and that malate is used to form pyruvate (Pgs. 450, 452).

Hultman et al. teaches that creatine phosphate is the substrate in muscular tissue which gives the fastest resynthesis of ATP and that formulations containing creatine include effervescent powders which may be dissolved in water (Column 1, lines 20-35, Column 2, lines 23-27).

St. Cyr et al. teaches that energy buildup in muscle cells is through oxidative phosphorylation which replenishes ATP by breakdown of circulating fatty acids, glucose and

Art Unit: 1616

intramuscular glycogen and triglycerides and anerobic phosphorylation which provides ATP from creatine phosphate, glucose and intramuscular glycogen via kinase reactions (Column 1, lines 29-43). It is taught that irrespective of the substrates used for the generation of ATP, ATP cannot be synthesized unless that precursors of the ATP molecule itself are available (Column 1, lines 60-64). It is taught that pentoses, such as ribose, allow athletes to exercise longer with greater energy and that combination with creatine, pyruvate, electrolytes and/or carbohydrates enhance the pentose benefit (Column 3, lines 10-57).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or method of using the same, comprising creatine, a phosphorous supplement which provides at least 75% of the recommended daily dose value per serving and a blood buffer. However, the prior art amply suggests the same as it is known in the art to prepare nutritional supplements containing creatine, phosphorus and blood buffers for increasing energy and increasing anaerobic work capacity. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of creatine, phosphorus, sodium, blood buffers, organic salts of creatine, Krebs cycle intermediates and precursors thereof, carbohydrates, pentoses would be effective increasing tissue cell energy and anaerobic work capacity and that after the initial administration that the increased anerobic work capacity could be maintained with lesser doses of the composition.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Art Unit: 1616

Conclusion

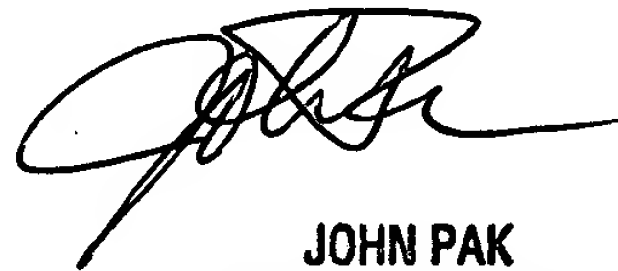
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

November 29, 2001



JOHN PAK
PRIMARY EXAMINER
GROUP 1600

